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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,799	08/24/2001	Bettina Mockel	32301WD195	9044

7590 09/09/2003

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	13

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/935,799	MOCKEL ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *12-26 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11 and 27* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☑ Other: attached alignments

DETAILED ACTION

Application Status

1. In response to the previous Office action, a written restriction requirement (Paper No. 11, mailed on June 4, 2003), Applicants filed an election received on June 17, 2003 (Paper No. 12). Thus, Claims 1-30 are pending in the instant Office action.

Election

2. Applicants' election with traverse of Group I, Claims 1-11 and 27, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that "a search for the subject matter in Group I is inextricably intertwined with the subject matter in the claims of the other Groups". This is not found persuasive because the searches are not co-extensive, as evidenced by the distinct class, subclass classifications. The search of additional subclasses would be burden to the Office to be examined together.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 are pending in the instant Office action. Claims 12-26 and 28-30 are withdrawn from further consideration as non-elected inventions. Claims 1-11 and 27 will be examined herein.

Priority

3. The instant application is granted the benefit of priority for the foreign application 100 42 051.6 filed in Germany on August 26, 2000 as requested in the declaration. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119(a)-(d), which papers have been placed of record in the file. Said papers are not in English and thus, cannot be used to provide evidence of an earlier effective filing date for the pending claims.

Information Disclosure Statement

4. The information disclosure statement filed on January 17, 2002 (Paper No. 10) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. Some citations have been corrected by the Examiner; no action is required by Applicants. The search report has been reviewed but is crossed out on the IDS since it is not printed on the face of a patent.

Declaration

5. The Examiner notes that the declaration filed October 24, 2001 (Paper No. 3) has the box checked "attached hereto" concerning the specification; however the specification was previously filed on August 24, 2001. This is considered a typographical error since the title and inventors names match that filed on August 24, 2001; the declaration is adequate for the instant application. No action is required by Applicants.

Sequence Compliance

6. By virtue of the sequence listing filed on February 7, 2002 (Paper No. 8) listing 7 sequences and the statement under 37 C.F.R. § 1.821(f), the instant application fully complies with the sequence rules.

Objections to the Specification

7. In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its

completeness is essential. The Examiner suggests the inclusion of the full name of the enzyme, carbon starvation protein A, and the source species, *Corynebacterium glutamicum,* for completeness.

8. The specification is objected to for being confusing with respect to the sequence listing. The sequence listing contains 7 sequences. Every SEQ ID NO is mentioned in the specification and/or the claims except SEQ ID NO: 5. It is unclear why said sequences are in the sequence listing if they are not described in the specification. All SEQ ID NOs in the sequence listing must be described in the specification. Appropriate correction is required.

9. The specification is objected to for having an inconsistency with respect to the use of the cstA gene. Throughout the specification and the claims, the *cstA* gene is enhanced or overexpressed for the increased production of lysine; however, in the Abstract, the gene is noted as being attenuated. Clarification and/or correction are required.

Claim Objections

10. Claim 5 is objected to for depending from a rejected claim.

11. Claim 8 is objected to for a typographical error. In line 3, the term "sequences" should be singular since only one SEQ ID NO follows the term.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-4, 6-7, and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the phrase "from coryneform bacteria" is unclear as to its metes and bounds. Does this phrase limit the claimed polynucleotides to those native to coryneform? Or can any polynucleotide that can be found in coryneform, recombinantly or otherwise (i.e., an *E. coli* gene can be on a plasmid transformed into coryneform) read on the claim? Clarification is required. The Examiner suggests the term ---native to--- for clarity.

13. Claims 1-4, 6-7, and 27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "which codes for the cstA gene" is unclear. Firstly, a polynucleotide sequence does not "code for" a gene; polynucleotides are genes that code for (or encode) polypeptides. Thus, this limitation is unclear. Secondly, which *cstA* gene is intended? The term "**the** cstA gene" (emphasis added) indicates a particular *cstA* gene, for example SEQ ID NO:1; however, tremendous breadth of structure in the claimed genus follows this term. Thirdly, items c and d are wholly unclear considering any encoding limitation since item c is drawn to the complement of a coding sequence and d is drawn to small fragments. Thus, the metes and bounds of the instant claims are unclear.

14. Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the activity of carbon starvation protein A" is unclear. What kind of activity is it? Is it an enzyme, a receptor? The specification offers no description of the term either directly or by reference. Thus, the metes and bounds of the term are wholly unclear. Clarification is required.

15. Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "further comprising ... sense mutations of neutral function" is unclear. Since a DNA's function is to encode a protein, does this phrase mean within the degeneration of the genetic code (already claimed in Claim 6, item ii)? Or is the retention of the function of the encoded protein intended? The phrase is wholly unclear. Moreover, must the DNA of Claim 6 also have this limitation or is it another option to be added to Claim 6 as implied by the item number "iv"? If it is another option added, Claim 7 does not further limit the parent claim appropriately. Clarification is required.

16. Claims 9-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "**the** cstA gene" (emphasis added) indicates a particular *cstA* gene; however, the breadth of the claims is unclear. Must the coryneform's own cstA gene be

enhanced? And must that be by an identical copy of cstA (i.e., is a *C. glutamicum* cstA sufficient to enhance cstA in *C. diphtheriae* or must the *C. diphtheriae* cstA be used)? Clarification is required.

17. Claims 9-10 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the enhanced gene are unclear. In the art, this could be accomplished by adding additional copies of the gene to "enhance" the gene. It is unclear if the intended scope is meant to include enhancing the amount and/or activity of the cstA gene in the host cell, such as by mutating the cstA gene to increase the stability of its polynucleotide transcript, which would then increase the amount of transcribed cstA protein in the cell. Thus, the scope of the instant claims are wholly unclear.

18. Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "A shuttle vector *Escherichia coli* DH5alphamcr/pED-K18mob2cstAexp" is unclear since the deposit number refers to a host cell; the Examiner suggests ---The shuttle vector in *Escherichia coli* DH5alphamcr/pED-K18mob2cstAexp--- for clarity.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-4, 6, 7, and 27 are rejected under 35 U.S.C. 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1-4 and 27 are drawn to polynucleotides having a particular structure without any clear function. Claims 6-7 require no particular structure due to the breadth of "hybridizes" in Claim 6, item iii, and no particular function.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

The instant specification discloses polynucleotides encoding polypeptides with at least 70% identity with SEQ ID NO: 2. Applicants have described a genus relating to said SEQ ID NO with both sequence identity limitations and functional limitations (i.e., having the activity of carbon starvation protein). However, the genus of the instant claims also contains polynucleotides within the sequence identity limitations, but having different function. Moreover, based on the unclear functional limitation in Claim 2, this claim is also included in the instant rejection. Applicants have not fully described a genus that has sequence identity limitations in the absence of functional limitations.

20. Claims 9-10 are rejected under 35 U.S.C. § 112, first paragraph, written description, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 is drawn to bacterium having enhanced cstA gene that is claimed solely by function and without any structural limitations.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could

predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

In the instant specification, genes encoding cstA are briefly described as having been obtained from *Corynebacterium glutamicum*. These genes are only described according to the functional characteristics of the enzymes they encode; no structural relationship is described or used in the claims. Thus, one of skill in the art would be unable to predict the structure of other members of this genus by virtue of the instant disclosure. Therefore, claims drawn to bacteria containing the genus of said genes are also not adequately described. The Examiner suggests inserting structural and, if necessary, functional language into the claims to describe the cstA gene to be enhanced.

21. Claims 1-4, 6, 7, 9-10, and 27 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for any polynucleotide encoding SEQ ID NO:2 (a cstA gene), does not reasonably provide enablement for polynucleotides encoding polypeptides having as little as 70% identity with SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as

routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

The instant specification teaches SEQ ID NO:2, a carbon starvation protein from *C. glutamicum*, and SEQ ID NO:1, a *C. glutamicum* gene exactly encoding SEQ ID NO:2. The art includes few examples of cstA encoding genes, with carbon starvation being mostly studied in *E. coli*. The art fully enables any DNA encoding SEQ ID NO:2 based on the degeneracy of the genetic code. While the instant specification describes and enables means for identifying other cstA genes using hybridization methods, etc., these methods do not enable one of skill in the art to make all, or a relevant portion of, the polynucleotide products within the scope of the claims because the ability to find a cstA gene, which is structurally related to SEQ ID NOs:1 and/or 2, is not equivalent to the ability to make a cstA gene as required by the statute (i.e., "make and use"). No description in the specification or the art provides particular residues whose encoding is

important within the disclosed sequence so that its cstA-nature is maintained. Thus, one of skill in the art would be unable to predict the structure of the other members of the genus in order to make such members. Therefore, the instant claims are not enabled to the full extent of their scope.

22. Claims 9-10 are rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for coryneform comprising an overexpression vector containing the cstA gene (a polynucleotide encoding SEQ ID NO:2), does not reasonably provide enablement for any cstA gene that is enhanced and/or overexpressed in coryneform by other means. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. To make the claimed product commensurate with the claimed scope would require undue experimentation.

The factors to be considered in determining whether undue experimentation is required are summarized above.

The instant specification teaches a cstA gene from *C. glutamicum* and transformation techniques used for coryneform host cell. Thus, one of skill in the art could readily produce expression vectors of the disclosed gene for overexpression in *C. glutamicum*. However, the claimed scope also includes using altered cstA genes such that the gene was enhanced (i.e., changing RNA transcript stability, protein stability, etc.). No examples, guidance, or direction is presented to enable one of skill in the art to produce such host cells. Moreover, it is wholly unpredictable how to produce such cstA genes for overexpression. Thus, the instant claims are not fully enabled.

23. Claim 11 is rejected under 35 U.S.C. § 112, first paragraph, enabling deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To practice the instant methods, one of skill in the art is required to have DSM 13671, which is disclosed as containing pEC-K18mob2cstAexp, of all the components to produce pEC-K18mob2cstAexp. The components are not readily available, and the deposit fails to fully enable the claims. While the instant specification contains limited deposit information, the requirements to enable such a deposit have not been fully met by the instant application. To enable the instant claims by enabling the deposit of DSM 13671, the following items are required: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and **full address** of the depository (37 C.F.R. § 1.801 - 1.809) (those which are in bold have not been fulfilled by the instant specification), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

24. Claims 1-4, 6-10, and 27 are rejected under 35 U.S.C. § 102(a) as being anticipated by Pompejus *et al.* (WO 01/00804 - -see IDS). The instant claims are drawn to polynucleotides similar to a nucleic acid encoding SEQ ID NO:2 and *C. glutamicum* that overexpress the cstA gene.

Pompejus *et al.* teach SEQ ID NO:13 that encodes SEQ ID NO:2 in the instant application (see attached alignment). SEQ ID NO:13 of Pompejus *et al.* is identical to a portion of SEQ ID NO:1 except for an insert of 13 nucleotides prior to the coding sequence (200-2515bp); moreover, SEQ ID NO:13 of Pompejus *et al.* does not include the first 86 nucleotides of the coding sequence for SEQ ID NO:2. Pompejus *et al.* describe this sequence as encoding a carbon starvation protein (see Table 1, page 56). Pompejus *et al.* also teach overexpression of SEQ ID NO:13 in *C. glutamicum* to produce lysine using overexpression vectors (see page 8).

25. Claims 1-4, 6-10, and 27 are rejected under 35 U.S.C. § 102(a) as being anticipated by Nakagawa *et al.* (EP 1108790 - -see IDS). The instant claims are drawn to polynucleotides similar to a nucleic acid encoding SEQ ID NO:2 and *C. glutamicum* that overexpress the cstA gene.

Nakagawa *et al.* teach SEQ ID NO:7061, a portion of which wholly encodes SEQ ID NO:2 in the instant application (see attached alignment); Nakagawa *et al.* also teach SEQ ID NO:727 that encodes a portion of SEQ ID NO:2)see attached alignment). SEQ ID NO: 7061 of Nakagawa *et al.* is identical to SEQ ID NO:1 except for an insert of 13 nucleotides prior to the coding sequence (200-2515bp). Nakagawa *et al.* describe SEQ ID NO:727 as encoding a carbon

starvation protein (see Table 1, page 72). Nakagawa *et al.* also teach overexpression of the disclosed sequences in *C. glutamicum* to produce the encoded polypeptides (see page 22).

26. Claims 1-3, 6, and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cole *et al.* (Deciphering the biology of Mycobacterium tuberculosis from the complete genome sequence. Nature (1998) 393:537-544). The instant claims are drawn to a DNA comprising at least 15 consecutive nucleotides of SEQ ID NO:1 that will hybridize to the complement of SEQ ID NO:1.

Cole *et al.* teach a 31859 bp DNA containing 29 consecutive nucleotides that are identical to a portion of SEQ ID NO:1 (see attached alignment). This portion will hybridize to the complement of SEQ ID NO:1.

Other Relevant Art

27. The following is cited to complete the record for the reasons noted:

a) Dubey *et al.* (CsrA regulates translation of the *Escherichia* coli carbon starvation gene, cstA, by blocking ribosome access to the cstA transcript. J. Bacteriol. (2003) 185(15):4450-4460) teaches an overview of carbon starvation protein lacking in the instant application.

Conclusion

28. Claim 5 is objected to. Claims 1-4, 6-11 and 27 are rejected for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 05, 2003